

Serial No. 10/086,068

Patent  
018484-002121USREMARKS

Claims 1-157 are pending in the application.

Restriction Requirement

In the Office Action of March 24, 2005, the Examiner has acknowledged receipt of Applicants' response of January 10, 2005 to the prior Election/Restriction Requirement. However, the Examiner has also indicated that the prior Election/Restriction Requirement dated September 9, 2004 has been withdrawn. In the Office Action of March 24, 2005, the claims have been newly divided into five (5) groups: Group I, claims 1-54, drawn to a method of treating rheumatoid arthritis, which comprises delivery of a DNA sequence to a host; Group II, claims 55-108, drawn to a method of treating systemic lupus erythematosus, which comprises delivery of a DNA sequence to a host; Group III, claims 109-130, drawn to a method of treating a connective tissue disorder, which comprises delivery of a DNA sequence to a host; Group IV, claims 131-142, drawn to a mammalian cell comprising a recombinant retroviral vector, which comprises a DNA sequence encoding IRAP; and Group V, claims 143-157, drawn to a method of inhibiting an IL-1 induced biological response in a mammal.

Applicants traverse this restriction requirement. Reconsideration and withdrawal thereof are earnestly requested. Applicants submit that there is not an undue burden placed upon the Examiner to search and consider all of the claims.

All of the claims in the present application are directed to methods of therapeutic or prophylactic treatment of connective tissue diseases. All of the claims revolve around the concept of using a nucleic acid sequence encoding gene products, which address one or more of the inflammatory, hypertrophic and erosive components of the disease, and combat one or more

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of these pathological components. Therefore, the claims are linked together so as to form a single invention. Accordingly, all of the claims should be examined together on the merits.

Although Applicants disagree with the Examiner, in order to be responsive to the outstanding restriction requirement, Applicants provisionally elect to prosecute Group V, claims 143-157, drawn to a method of inhibiting an IL-1 induced biological response in a mammal. Applicant specifically preserves the right to prosecute the non-elected claims.

**Election of Species**

In addition to the above-mentioned restriction groups, the Examiner has further placed species restriction on claims of Groups I-V and indicated that a single disclosed species of vectors must be elected from the following list of vectors: a) non-viral vector, b) a retroviral vector, c) adenovirus vector, d) an adeno-associated vector, e) herpes simplex virus vector, f) an SV40 vector, g) polyoma virus vector, h) papilloma virus vector, i) picornavirus vector, j) vaccinia virus vector, k) Moloney murine leukemia virus, and l) MFG-IRAP. Applicants traverse this requirement. Reconsideration and withdrawal thereof are earnestly requested.

Various vectors can be used in the presently claimed invention to carry a nucleic acid sequence, which is to be transferred to and expressed in the mammalian host cell. Depending on the several factors such as the kind of the host, the kind of the nucleic acid sequence, and etc., different kinds of vectors can be used for better gene delivery and expression. Therefore, it is not reasonable to divide all of these vectors into individual species. Further, Applicants submit that there is not an undue burden placed upon the Examiner to search and consider all of the species.

Although Applicants disagree with the Examiner, in order to be responsive to the outstanding species requirement, Applicants provisionally elect to prosecute species c)

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“adenovirus vector”. It is believed that provisionally elected Group V claims 143-157 are readable thereon.

The Examiner has also placed species restriction on claims of Groups I-III, and V and indicated that a single disclosed species of DNA sequences encoding a biologically active gene product must be elected from the following list: a) IL-1 receptor antagonist protein, b) IL-4, c) IL-10, d) IL-1 soluble receptor, e) TNF  $\alpha$  soluble receptor, f) TIMP, g) soluble ICAM-1, h) soluble CD44, i) soluble CD18, j) superoxide dismutase, k) IGF  $\alpha$ , l) TGF  $\beta$ , m) collagen, and n) IRAP. Applicants traverse this requirement. Reconsideration and withdrawal thereof are earnestly requested.

Various nucleic acid sequences can be used in the presently claimed invention to treat connective tissue diseases. To provide therapeutic or prophylactic relief and treat connective tissue diseases, the presently claimed invention deliver a nucleic acid sequence and express a specific gene *in vivo*. The nucleic acid sequence should encode gene products which address one or more of the inflammatory, hypertrophic and erosive components of the disease. Nucleic acid sequences which combat one or more of these pathological components may be utilized in practicing the presently claimed invention. Therefore, it is not reasonable to divide all of these nucleic acid sequences encoding a biologically active gene product into individual species. Further, Applicants submit that there is not an undue burden placed upon the Examiner to search and consider all of the species.

Although Applicants disagree with the Examiner, in order to be responsive to the outstanding species requirement, Applicants provisionally elect to prosecute species e) “IL-10”. It is believed that provisionally elected Group V claims 143-157 are readable thereon.

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The Examiner has further placed species restriction on claims of Group III, and indicated that a single disclosed species of connective tissue diseases or disorders must be elected from the following list: a) Sjorgen's syndrome, b) polymyositis-dermatomyositis, c) systemic sclerosis, d) vasculitis syndromes, e) juvenile rheumatoid arthritis, f) ankylosing spondylitis, g) psoriatic arthritis, h) osteogenic imperfecta, i) Paget's disease, and j) inflammatory bowel disease.

Applicants traverse this requirement. Reconsideration and withdrawal thereof are earnestly requested.

All of the above-listed diseases or disorders are pathogenically related to connective tissue and may be treated by the present invention since they may be affected by common causative agents. Some of the causative agents may be cytokines. For example, interleukin-1 (IL-1) has been known to play a role in numerous diseases and disorders, in particular, disorders accompanied by inflammation. Therefore, it is not reasonable to divide all of these related diseases or disorders into individual species. Further, Applicants submit that there is not an undue burden placed upon the Examiner to search and consider all of the species.

Although Applicants disagree with the Examiner, in order to be responsive to the outstanding species requirement, Applicants provisionally elect to prosecute species e) "juvenile rheumatoid arthritis". It is believed that Group III claims 109-130 are readable thereon.

In summary, in response to the outstanding restriction requirement, Applicants provisionally elect to prosecute Group V, claims 143-157 with species d) adenovirus vector and e) IL-10 for prosecution on the merits, with traverse. Applicants specifically preserve the right to prosecute the non-elected claims.

Accordingly, early examination on the merits is respectfully requested.

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The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR §§ 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. 502486.

Respectfully submitted,

JHK Law

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